



American Society for Pharmacy Law

FRAUD, WASTE & ABUSE

Ranbaxy pleads guilty to multiple felony charges and agrees to pay \$500 million in settlement over adulterated drugs

The Department of Justice announced on May 13 that Ranbaxy USA Inc., a subsidiary of India's generic manufacturer, Ranbaxy Laboratories Ltd., has pleaded guilty to 3 felony violations of the FDCA and 4 felony counts of "knowingly making false statements to the FDA." The charges arise from the distribution and sale of batches of isotretinoin, gabapentin, and ciprofloxacin in 2005 and 2006 that were manufactured in India under conditions that rendered them adulterated. The false statements included reports of stability tests for cefaclor, cefadroxil, amoxicillin, and amoxicillin and clavulanate potassium products that misstated the dates on which the tests were conducted.

The settlement included a criminal fine and forfeiture of \$150 million, and \$350 million to settle state and federal civil claims under the False Claims Act. [USDOJ News. Generic drug manufacturer Ranbaxy pleads guilty and agrees to pay \$500 million to resolve false claims allegations, cGMP violations and false statements to the FDA, 2013 May 13; <http://1.usa.gov/10tXfUu>; U.S. v. Ranbaxy USA, Inc., JFM-13-CR-0238 (D. Md.); U.S. ex rel. Thakur v. Ranbaxy Laboratories Ltd., No. JFM-07-962 (D. Md.)]